510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE

A. 510(k) Number:
K042331

B. Purpose of Submission:
To include the testing of telithromycin against non-fastidious gram positive organisms on the Pasco MIC and MIC/ID Panels

C. Analyte:
Telithromycin (0.015-4 ug/mL) AST

D. Type of Test:
Quantitative Antimicrobial Susceptibility Test (AST) growth based fluorescence

E. Applicant:
Pasco Laboratories-BD Diagnostic Systems

F. Proprietary and Established Names:
Pasco MIC and MIC/ID Panel

G. Regulatory Information:

1. Regulation section:
   866.1640 Antimicrobial Susceptibility Test Powder
2. Classification:
   II
3. Product Code:
   JWY-manual readings of AST testing of >16 hour incubation
4. Panel:
   83 Microbiology

H. Intended Use:

1. Intended use(s):
   Pasco MIC and MIC/ID panels are used for quantitatively measuring the susceptibility of rapidly growing aerobic and facultative anaerobic bacterial pathogens to a battery of antimicrobial agents and determining the biochemical identification of these organisms.

   The Gram-Negative MIC/ID, the Gram-Negative MIC/ID II and Gram-Positive MIC/ID Panel contain appropriate batteries of antimicrobial agents and biochemical substrates currently used for determining antimicrobial susceptibility and biochemical identification of various organisms.
2. Indication(s) for use:
   The indication is for the addition of the antimicrobial telithromycin at concentrations of 0.015-4 ug/mL to the Gram Positive Pasco Panels for use in testing *Staphylococcus aureus.*
3. Special condition for use statement(s):
   The ability of the Pasco MIC and MIC/ID Panels to detect resistance to telithromycin among *Staphylococcus aureus* is unknown because the current absence of data on resistant isolates precludes defining any category other

than "susceptible". Strains yielding MIC results other than susceptible should be submitted to a reference laboratory for further testing.

For Prescription Use Only

4. Special instrument Requirements:
   Not applicable

I. Device Description:

Pasco MIC panels are multi-well plastic microtitre plates. Various concentrations of antimicrobics are dispensed into the Pasco microdilution panels and the panels are then frozen. Inoculum is prepared in saline and equated to a 0.5 McFarland standard. Panels are thawed prior to use, and inoculated with the test organisms. Plates are incubated for 16-24 hours at 35° in a non-CO^2 incubator and are then observed for visible growth or color changes (ID portion). The lowest concentration of each antimicrobial agent with no apparent visible growth of the test organism is recorded as the minimum inhibitory concentration (MIC). Only manual readings are performed using an indirect lighted background viewer.

Inoculation procedures include the Direct Turbidity Standard method, with recommendations to use a spectrophotometer to adjust the final inoculum concentration equal to the 0.5 McFarland standard and the Director™ Inoculation System. The Director™ Inoculation System is used to prepare a standardized inoculum by eliminating the task of turbidity adjustment and the need for an active broth culture.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   Pasco MIC Panels with Daptomycin
2. Predicate K number(s):
   K041214
3. Comparison with predicate:

Similarities		
Item	**Device**	**Predicate**
Intended use	an *in vitro* diagnostic product for clinical susceptibility testing of clinical organisms.	same
Inoculum	Prepared from colonies using the direct inoculation method	same
Panel type	Frozen panels	same
Inoculation method	Direct equated to a 0.5 McFarland & Director™	same
Incubation	16-24 hours	same
Reading method	Visual growth	same
	Difference	
Item	**Device**	**Predicate**

Antibiotic	Serial dilutions of telithromycin	Serial dilutions of daptomycin

K. Standard/Guidance Document Referenced (if applicable):

"Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems; Guidance for Industry and FDA"; NCCLS M7 (M100-S14) "Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically; Approved Standard"

L. Test Principle:

The test panels are dependent on the growth of the organisms in the presence of the antibiotics. The minimum inhibitory concentration (MIC) is determined by observing the lowest dilution of antimicrobial agent that inhibits growth of the organism.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Reproducibility testing was performed on 10 organisms tested in triplicate at three sites on three separate days with a different inoculum prepared for each test. The testing demonstrated an intra- and inter- site reproducibility of 100% for the routine turbidity inoculum method and the Director™ Inoculum method.

b. Linearity/assay reportable range:

Not applicable

c. Traceability (controls, calibrators, or method):

The recommended QC isolates were tested daily with acceptable results with the reference method. Quality control was also performed at all sites on each day of testing. The Pasco results demonstrate that the system can produce QC results in the recommended range.

ORGANISM	**Conc ug/mL**	**Reference**	**Routine**	**Director™**
S. aureus ATCC 29213 Range 0.06-0.25 ug/ml	0.03			
	0.06	35	55	13
	0.12	103	82	97
	0.25		1	
	0.5			
E. faecalis ATCC 29212 Range 0.016-0.12 ug/ml	<0.016		1	
	0.03	136	136	109
	0.06	2	1	1
	0.012			
	0.25			

The Nephelometer was used at each site to standardize the inoculum and it was calibrated each time prior to setup. Colony counts were performed on QC isolates periodically with a mean concentration range of 2-7 x 10^5. Colony counts were performed on

reproducibility isolates using the Director™ Inoculum method yielding a mean range of 1 x 10^5 cfu/ml to 6 x 10^5cfu/ml. The test device had a growth rate of >95%.

d. Detection limit:
Not applicable

e. Analytical specificity:
Not applicable

f. Assay cut-off
Not applicable

2. Comparison studies:

a. Method comparison with predicate device:
Broth dilutions were made using 0.85% saline solution and adjusted to a McFarland 0.5 standard and then transferred into a tube of diluent with tween. Broth reference panels prepared according to the recommendations of the NCCLS M-7 document (Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically) were used to compare to the Pasco panel results. Testing was performed at 3 sites and included fresh and stock clinical isolates and a set of challenge organisms. A total of approximately 800 organisms were tested. Performance was based on comparative testing of the system with *S. aureus* which is the approved indication for use. The following are the comparative results of test accuracy of the Pasco system for *S. aureus* MRSA/MSSA testing as compared to the reference method.

	total	EA	%EA	Total evaluable	EA of evaluable	%EA	CA	%CA	#R	min	maj	vmj
Clinical	**77**	**77**	**100**	**73**	**73**	**100**	**77**	**100**	**4**	**0**	**0**	**0**
Challenge	**38**	**38**	**100**	**38**	**38**	**100**	**38**	**100**	**0**	**0**	**0**	**0**
Combined	**115**	**115**	**100**	**111**	**111**	**100**	**115**	**100**	**4**	**0**	**0**	**0**

EA-Essential agreement
CA-Category agreement
R- Resistant isolates
maj-major discrepancies
min-minor discrepancies
vmj-very major discrepancies

EA is when there is agreement between the reference method and the MIC and MIC/ID Panel within plus or minus one serial two-fold dilution of antibiotic. CA is when the interpretation of the reference method agrees exactly with the interpretation of the Pasco result. The %EA is acceptable when compared to the reference method as described in the FDA guidance document, "Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems; Guidance for Industry and FDA".

The FDA approved indication for use of telithromycin when testing *Staphylococcus aureus* is for methicillin and erythromycin susceptible strains only. Of the clinical isolates, both MRSA (methicillin resistant *S. aureus*) and MSSA (methicillin susceptible

S. aureus) strains were tested. A few of the strains were erythromycin resistant.

b. Matrix comparison:
Not applicable

3. Clinical studies:
   a. Clinical sensitivity:
   Not applicable
   b. Clinical specificity:
   Not applicable
   c. Other clinical supportive data (when a and b is not applicable):
   Not applicable
4. Clinical cut-off:
   Not applicable
5. Expected values/Reference range: (Interpretive Criteria)
   Staphylococcus aureus ≤0.25 (S)
   The Interpretative criterion, QC isolates and the expected ranges are the same as recommended by FDA.

N. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.